Supreme Court, U.S.
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No. _____

OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

ST. LOUIS UNIVERSITY, a corporation,

Petitioner,

—v.—

UNITED STATES OF AMERICA,

Respondent.

ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED FOR REVIEW

1. In light of *Berkovitz v. United States*, 486 U.S. 531 (1988), is the United States Government liable under the Federal Tort Claims Act for oral-polio-vaccine-associated injury upon the Government's concession that it released the injury-causing polio vaccine in violation of mandatory federal vaccine safety regulations?

2. Given that the Fourth Circuit's decision below dismissing petitioner's oral-polio-vaccine-associated injury claims against the Government is in direct conflict with the precedent of the Third, Fourth, Sixth, Eighth, and Ninth Circuits subjecting the Government to liability for oral-polio-vaccine-associated injury where the Government released the injury-causing polio vaccine in violation of mandatory federal vaccine safety regulations, should the Supreme Court resolve this conflict?

3. Does not the Fourth Circuit's decision below enabling the Government to escape liability for violating the mandatory federal vaccine safety regulations undermine the uniform application of those regulations by conditioning liability thereunder on conflicting proximate cause standards?

LIST OF PARTIES IN COURT BELOW

1. St. Louis University, a corporation, Petitioner;
2. American Cyanamid Company, a corporation;*
3. United States of America, Respondent.

CORPORATE DISCLOSURE STATEMENT

St. Louis University makes this corporate disclosure statement pursuant to Supreme Court Rule 29.6:

1. St. Louis University has no parent corporation.

2. No publicly-held corporation owns 10 percent or more of the stock of St. Louis University.

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* The United States District Court below addressed in a single opinion the contribution claims of St. Louis University against both American Cyanamid Co., the vaccine manufacturer, and the Untied States Government, which tested and approved the vaccine. *St. Louis University v. United States*, 182 F. Supp. 2d 494 (D. Md. 2002). However, the Fourth Circuit addressed the appeals of those claims against each defendant in two separate opinions. *United States v. St. Louis University*, 336 F.3d 294 (4th Cir. July 16, 2003); *American Cyanamid Co. v. St. Louis University*, 336 F.3d 307 (4th Cir. July 16, 2003). Likewise, petitioner submits two separate petitions for certiorari for review of each of those two judgments. *See* Sup. Ct. R. 12.4 (single petition for certiorari for review of two judgments only appropriate where two judgments "involve identical or closely related questions").

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* Reprinted in pertinent part at Appendix E. To be consistent with the citation of these federal regulations by the District Court below ever since he presided over the multi-district *Sabin* OPV cases, petitioner will cite to these OPV regulations by their original number, even though they were later renumbered in 21 C.F.R. §§ 6030.10-6030.17. *See In re Sabin Oral Polio Vaccine Products Liability Litigation*, 763 F. Supp. 811, 813 n.2 (D. Md. 1991) ("*Sabin II*") ("I will cite to them (as I did in my earlier opinion) by their original number").

CITATIONS OF OPINIONS AND ORDERS IN CASE

The opinion of the United States Court of Appeals for the Fourth Circuit, *United States v. St. Louis University,* is reported at 336 F.3d 294 (4th Cir. July 16, 2003), and is reprinted as Appendix A.

The opinion below of the United States District Court for the District of Maryland, reported at 182 F. Supp. 2d 494 (D. Md. 2002), and reprinted as Appendix B, had granted partial summary judgment in favor of St. Louis University against the United States. The Fourth Circuit reversed that opinion, and directed entry of final judgment in favor of the United States. In accordance with that directive of the Fourth Circuit, the District Court on remand entered judgment for the United States against St. Louis University. *See* Order of District Court (Sept 12, 2003), reprinted as Appendix C.

JURISDICTIONAL STATEMENT

The judgment of the United States Court of Appeals for the Fourth Circuit was entered on July 16, 2003. On July 28, 2003, petitioner timely filed a Petition for Rehearing *en banc*. The court below entered an Order, reprinted as Appendix D, denying that petition on August 12, 2003.

This petition for a writ of certiorari is filed within 90 days of the Order of the court below denying rehearing *en banc*, so this Court has jurisdiction to review the judgment of the Fourth Circuit on petition for certiorari under Section 1254(1) of the Judicial Code. 28 U.S.C. § 1254(1).

FEDERAL REGULATIONS INVOLVED

Danny Callahan contracted polio after receiving the excessively neurovirulent Orimune oral polio vaccine ("OPV") that the Government released to the public in violation of mandatory federal OPV regulations.[1] *St. Louis University* v. *United States*, 182 F. Supp. 2d at 498; *see also In re Sabin Oral Polio Vaccine Products Liability Litigation*, 774 F. Supp. 952, 957-58 (D. Md. 1991) (*"Sabin III"*) (holding Government liable for plaintiffs' injuries proximately caused by Government's release of excessively neurovirulent Orimune vaccine in violation of mandatory federal OPV neurovirulence regulations), ***affirmed***, *In re Sabin Oral Polio Vaccine Products Liability Litigation*, 984 F.2d 124, 127 (4th Cir. 1993) (*"Sabin IV"*). Specifically, the Government "violated 42 C.R.F. § 73.114(b)(1)(iii) by releasing [Orimune] vaccine lots that exceed the reference vaccine in neurovirulence." *Sabin IV*, 984 F.2d at 127.[2] As explained by the Supreme Court, *neurovirulence* "refers to the vaccine's *ability to cause paralytic poliomyelitis*." *Berkovitz v. United States*, 486 U.S. 531, 544 n.9 (1988) (emphasis added). If the Government had not violated those mandatory federal OPV neurovirulence regulations, the excessively neurovirulent Orimune vaccine that caused Danny to contract paralytic poliomyelitis *would never have been released at all*.[3]

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[1] Federal District Judge Frederick Motz presiding over this case also presided over the *Sabin* multi-district Orimune cases where he "determined that under a tort regime, identical in all relevant respects to the one at issue here, an injury, identical to the one at issue here, was proximately caused by tortious conduct identical to that alleged here." *United States v. St. Louis University,* 336 F.3d at 304 (Luttig, J., dissenting).

[2] As these federal regulations are lengthy, their pertinent text will be reproduced verbatim as Appendix E.

[3] St. Louis University ("SLU") is the plaintiff in this contribution action, as SLU paid a $ 16 million Missouri state-court judg-

STATEMENT OF THE CASE

The Supreme Court should grant certiorari to enforce binding Supreme Court and Fourth Circuit precedent, resolve the conflict between the panel below and the Third, Sixth, Eighth and Ninth Circuits, enforce Congressional intent as stated in 42 U.S.C. 262(d),[4] and uphold public confidence in the federal regulatory system itself by subjecting the Government to liability for violating its own mandatory federal OPV safety regulations, which were enacted to protect public health and prevent the affliction—paralytic poliomyelitis—caused here by their violation.

The divided Fourth Circuit panel below disregarded Congressional intent to insure the safety, purity and potency of vaccines, and undercut public confidence in the fed-

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ment to the family of Danny Callahan who contracted paralytic poliomyelitis after ingesting the polio vaccine. After paying the state-court judgment, SLU sued the Government and vaccine manufacturer in contribution.

[4] In *Berkovitz*, this Court construed 42 U.S.C. § 262(d) as follows:

> In deciding whether to issue a license, the DBS is required to comply with certain statutory and regulatory provisions. The Public Health Service Act provides:
>
> > "Licenses for the maintenance of establishments for the propagation or manufacture and preparation of products [including polio vaccines] may be issued only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they meet such standards. All such licenses shall be issued, suspended, and revoked as prescribed by regulations. . . ." § 351(d), 58 Stat. 702-703, as amended, 42 U.S.C. § 262(d).

Berkovitz, 486 U.S. at 541-42.

eral regulatory system itself by allowing the Government to escape liability for violating its own mandatory OPV regulations. While conceding that the Government was not allowed to release this polio vaccine whose excessive "ability to cause paralytic poliomyelitis" violated mandatory federal OPV regulations, and further conceding that this Orimune vaccine was the cause-in-fact of Danny's paralytic poliomyelitis,[5] the Fourth Circuit held that plaintiff could *not* prove that the Government's release of this excessively neurovirulent vaccine was a *proximate cause* of Danny's paralytic poliomyelitis unless plaintiff proved that Danny "would not have contracted polio . . . from a vaccine that satisfied the government's neurovirulence requirements." *United States v. St. Louis University,* 336 F.3d at 303. The Fourth Circuit adopted the position of the Government that the release of the vaccine whose excessive ability to cause paralytic poliomyelitis violated the mandatory federal OPV safety regulations—and in fact *did* cause Danny's paralytic poliomyelitis—was *not* a proximate cause of Danny's paralytic poliomyelitis. *Id.* at 303-304.

To be clear, it is undisputed in this case that the United States Government released the Orimune vaccine of live polio in violation of mandatory federal OPV safety regulations. *Sabin III*, 774 F. Supp. at 957 (finding the Government "approved [Orimune] vaccine exceeding the neurovirulence criteria which had been established in the regulations as a means for defining acceptable risk. They were fully aware that the vaccine did not pass the regulatory tests"). Specifically, because that vaccine's neurovirulence—its "ability to cause par-

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[5] *See United States v. St. Louis University,* 336 F.3d at 302 (on "the question of causation-in-fact" the appellate panel accepted "[t]he district court's conclusion that Danny Callahan would not have contracted polio 'but for' the government's action").

alytic poliomyelitis"—violated the limits set forth in 42 C.F.R. § 73.113(b) and 42 C.F.R. § 73.114(B) (1) (iii), the Government was not allowed to release that vaccine. *Berkovitz,* 486 U.S. at 548, n.13 ("if an employee knew that [the Orimune] lot did not comply with these standards, he would have no discretion to approve the release of the lot"). And it is undisputed that this excessively neurovirulent Orimune vaccine was given to three-month old Danny Callahan, causing him paralytic poliomyelitis. *St. Louis University* v. *United States*, 182 F. Supp. 2d at 496-97.

The Federal District Court below found that the Government's violations of its own mandatory regulations constituted negligence and proximately caused Danny's paralysis. *St. Louis University v. United States*, 182 F. Supp.2d at 499 (D. Md. 2002) ("If the government had not wrongfully approved the seed from which the vaccine was derived, Callahan would never had been administered a dose of Orimune and never would have contracted polio"). Plaintiff sustained the burden of proof necessary to establish liability. *Id.*

The District Court reasoned that by releasing the excessively neurovirulent vaccine in violation of its own regulations, Government officials "increased the risk that several more individuals would contract polio as a result of exposure to the OPV than would have done so if the OPV regulations had been strictly followed." *Id.* at 503. The Government officials thus wrongly "*arrogated to themselves the power to define what constituted an acceptable [public health] risk, thereby undermining the rule of law and threatening long-term public confidence in the regulatory system itself.*" *Sabin III*, 774 F. Supp. at 957 (emphasis added). Thus, the District Court perceived that the "claim against the United States . . . turns on a more fundamental principle" than redressing

the injuries of one individual; for this claim against the United States is about "the necessity of upholding the rule of law" and public confidence in the federal regulatory system itself. *St. Louis University v. United States*, 182 F. Supp.2d at 502.

Likewise, the United States Supreme Court, *Berkovitz v. United States*, 486 U.S. 531, 546-48 (1988), Third Circuit, *Berkovitz by Berkovitz v. United States*, 858 F.2d 122, 124 (3d Cir. 1988), (*on remand*), *Griffin v. United States*, 500 F.2d 1059, 1065-70 (3d Cir. 1974), Fourth Circuit, *In re Sabin Oral Polio Vaccine Products Liability Litigation*, 984 F.2d 124, 128 ("*Sabin IV*") (4th Cir. 1993), Sixth Circuit, *Schindler v. United States*, 661 F.2d 552, 560 (6th Cir. 1981), Eighth Circuit, *Loge v. United States*, 662 F.2d 1268, 1273-74 (8th Cir. 1981), and Ninth Circuit, *Baker v. United States*, 817 F.2d 560, 566 (9th Cir. 1987), all subjected the Government to liability under the Federal Tort Claims Act ("FTCA") for violating its own mandatory OPV regulations by not complying with the licensing requirement and allowing the vaccine manufacturer to receive a license even without furnishing the safety data.

By permitting the Government to evade liability by forcing plaintiff to prove an unprovable proximate cause standard, the Fourth Circuit panel decision below thereby disregards binding precedent of both the United States Supreme Court and the Fourth Circuit, and conflicts with precedent of the Third, Sixth, Eighth and Ninth Circuits, which all subjected the Government to FTCA liability for violating its own mandatory federal OPV regulations.

SUMMARY OF FACTS

St. Louis University ("SLU") paid a $ 16 million Missouri state-court judgment to the family of Danny Callahan who contracted paralytic poliomyelitis after ingesting the Orimune polio vaccine. *St. Louis University v. United States*, 182 F. Supp.2d at 496-98; *United States v. St. Louis University*, 336 F.3d at 296-97. Approximately one month after receiving the dose of Orimune, Danny developed a fever and perirectal abscesses. *Id.* He was treated at Cardinal Glennon Hospital by SLU employees. *Id.* That judgment paid by SLU arose from SLU employee's actions in treating 3-month old Danny Callahan. *Id.* Although the abscesses improved, Danny's legs and left arm were permanently paralyzed. *Id.* The polio virus was a mixture of three different types, known as Type I, Type II and Type III, to combat the three types of wild virus, Type I, Type II and Type III. Danny's stools were tested and the doctors, and the Court below, concluded that Danny contracted paralytic poliomyelitis Type III from the Orimune vaccine. The Government conceded this fact. It is only the Type III component which had excessive neurovirulence during the applicable time when Danny Callahan and Kevan Berkovitz received the Orimune vaccine. *Id.*

SLU filed a contribution action against the United States in the Federal District of Maryland, asserting the Government proximately caused Danny's paralytic poliomyelitis by releasing the excessively neurovirulent Orimune polio vaccine in violation of its own mandatory OPV neurovirulence regulations. *Id.* If the Government had complied with its own mandatory OPV neurovirulence regulations, the Orimune vaccine would never have been released at all, and Danny Callahan would never have been exposed to the Orimune vaccine that caused him paralytic poliomyelitis. *Id*; *see also*, *Sabin*

III, 763 F. Supp. at 821-824 (holding Government liable for plaintiffs' paralytic poliomyelitis proximately caused by Government's release of excessively neurovirulent Orimune vaccine in violation of mandatory federal OPV safety regulations), ***affirmed***, *Sabin IV*, 984 F.2d at 127.

THE DISTRICT COURT DECISION:

St. Louis University v. United States, 182 F. Supp. 2d 494 (D. Md. 2002)

The District Court found that by releasing the Orimune vaccine lots whose "neurovirulence test results exceeded the regulatory criteria, DBS[6] increased the risk of harm to persons who were vaccinated." *St. Louis University v. United States*, 182 F. Supp. 2d at 501 (citing *Sabin III*, 774 F. Supp. at 955). In making that determination, the District Court found that "the neurovirulence criteria of the OPV regulations—which the government itself had adopted—provided the 'best available scientific standard' for determining excessive neurovirulence and that the government had therefore increased the risk of harm to the public." *Id.* at 502. By approving the Orimune vaccine whose 'ability to cause paralytic poliomyelitis' exceeded "the OPV regulations, the United States had breached its duty to the members of the public, which it had assumed by virtue of its undertaking to regulate a potentially hazardous condition for the benefit of others" under the Good Samaritan doctrine of § 324A of the Restatement (Second) of Torts. *St. Louis University v. United States*, 182 F. Supp. 2d at 502.

Once the District Court found that the United States had breached its duty by increasing its risk of harm to

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[6] Department of Biological Services ("DBS") of the National Institutes of Health of the U.S. Department of Health and Human Services.

the public, the District Court found that the United States proximately caused Danny's paralytic paralysis because "[i]f the government had not wrongfully approved the seed from which the vaccine was derived, Callahan would never have been administered a dose of Orimune and would never had contracted polio"—because the excessively neurovirulent vaccine given to Danny would never have been released at all. *Id.* at 499, 502.

Moreover, the District Court found that this case is about even more than redressing the injuries of one individual, it is about the "fundamental principle . . . of upholding the rule of law" and public faith in the federal regulatory system. *Id.* at 502. For the Government officials responsible for implementing the mandatory OPV regulations "arrogated to themselves the power to define what constituted an acceptable [public health] risk" when they violated the mandatory federal OPV regulations by releasing the excessively neurovirulent Orimune vaccine. *Id.* at 502-503 (citing *Sabin III*, 774 F. Supp. at 957). Those federal officials "were fully aware that the vaccine did not pass the regulatory tests," *Sabin III*, 774 F. Supp. at 957, and thus had no discretion to approve the release of the lot of excessively neurovirulent live polio vaccine in violation of the mandatory federal safety regulations. *Berkovitz*, 486 U.S. at 547, n.13 ("if an employee knew that a lot did not comply with these [neurovirulence] standards, he would have no discretion to approve the release of the lot"). Holding that the federal mandatory safety regulations themselves, and not the whims of Government bureaucrats, define what is an "acceptable [public health] risk," Judge Motz concluded:

> [I]n taking the actions they did, the [Government] increased the risk that several more individuals would contract polio as a result of exposure to OPV than would have done so if the OPV regulations had

> been strictly followed. It may well be that the rest of us were beneficiaries of a resultant harm suffered by a few. For that very reason, it is proper that we collectively be held liable for our government's actions.

St. Louis University v. United States, 182 F. Supp. 2d at 503.

THE 2-1 FOURTH CIRCUIT PANEL DECISION: *United States v. St. Louis University,* 336 F.3d 294 (4th Cir. July 16, 2003)

On appeal, the Government agreed that it was "bound by the findings of the *Sabin* cases that it breached its duty by violating the OPV regulations." *United States v. St. Louis University,* 336 F.3d at 301. The 2-1 Fourth Circuit decision likewise accepted the findings below that (1) the Government released the excessively neurovirulent Orimune vaccine in violation of the mandatory federal OPV neurovirulence regulations;[7] (2) this excessively neurovirulent Orimune vaccine was received by three-month old Danny Callahan;[8] (3) this Orimune vaccine whose excessive "ability to cause paralytic poliomyelitis" violated the OPV regulations did in fact cause paralytic poliomyelitis in Danny;[9] and (4) had the

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[7] *United States v. St. Louis University,* 336 F.3d at 298 (accepting district court's finding that "the vaccine seeds from which the [Orimune] lots were derived did not meet the neurovirulence standards set forth in the governing regulations").

[8] *United States v. St. Louis University,* 336 F.3d at 298 ("The Orimune vaccine received by Danny Callahan was derived from one of the vaccine seeds that the district court in the *Sabin* cases concluded were improperly approved by the government").

[9] *United States v. St. Louis University,* 336 F.3d at 297 ("doctors ultimately concluded that Danny suffered from vaccine-associated polio").

Government not violated its own federal OPV regulations, the excessively neurovirulent Orimune vaccine which Danny received would never have been released at all.[10]

Then, despite the fact that the 2-1 panel accepted these findings of the District Court, the 2-1 Panel allowed the Government to escape liability by holding plaintiff to an impossible proximate cause standard, one which directly contradicts the mandate of the Congressional statute to insure the safety, purity and potency of the vaccine:

> As to proximate cause, . . . to show that Danny's polio was caused by the government's regulatory violations, we conclude that SLU was required to establish that Danny likely would not have contracted polio . . . from a vaccine that satisfied the government's neurovirulence standards.

United States v. St. Louis University, 336 F.3d at 303.[11]

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[10] *United States v. St. Louis University,* 336 F.3d at 298(accepting district court's finding that Government "violat[ed] its own regulatory standards [by] approving for release vaccine derived from seeds that exceeded the neurovirulence standards"); *see also, id.* at 306 (Luttig, J., dissenting) (explaining that had the Government complied with the OPV regulations, "none of the offending vaccine would have been distributed at all").

[11] While the Fourth Circuit panel here purported to apply Missouri law, this test is inconsistent with the proximate cause standard of Missouri law, which adopts the standard of Restatement(Second) of Torts § 431 (conduct is proximate cause of injury if it "is a substantial factor in bringing about the harm"). S*ee Todd v. Watson*, 501 S.W. 2d 48, 52 (Mo. 1973) (citing Rest. (2d) § 431: "To be a legal cause of harm to another, one's conduct must be a substantial factor in brining about the harm"); *see also Robinson v. Missouri State Highway & Transp. Comm'n*, 24 S.W.3d 67, 78 (Mo. Ct. App. 2000) (per curiam) (proximate cause test is whether "the injury appears to be the reasonable and probable consequence of the act or omission of the defendant . . . . It is only necessary that the party charged knew or

It is clear that if the Sabin vaccine were not available, Danny Callahan, like every other American child, would have been inoculated with 100 per cent safe vaccine—the Salk vaccine, which according to the Institutes of Medicine, in 1997, was equally effective as the Sabin Orimune vaccine with the same duration of immunity, and, as to the individual recipient, gave the same benefits. The only reason Sabin vaccine was utilized was because it had the capacity to spread to other people; in some instances causing polio, and in other instances causing immunity. Ever since the Salk vaccine has been utilized in the United States since 1999, there has not been a single case of vaccine-induced polio to any individual whether it be through receipt and/or contact, nor has there been a wild case of polio during the same time period.

The 2-1 Panel thus imposed the proximate cause standard urged by the Government that the District Court below had already rejected in this case and in the *Sabin* cases as logically "unknowable and unprovable." *St. Louis University v. United States*, 182 F. Supp.2d at 502 ("Whether or not an oral polio vaccine that compiled with the OPV regulations would have caused Callahan and the plaintiffs in the other Sabin cases to contract polio ultimately is unknowable and unprovable"). Given that plaintiff could never prove that unprovable proximate cause standard, the 2-1 Panel below reversed and remanded for entry of final judgment in favor of the Government, declaring that "there is no evidence that the

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should have known there was an appreciable chance some injury would result") (internal citations omitted). And petitioner contends that by violating the OPV regulations by releasing the excessively neurovirulent vaccine, the Government knew or should have known that there was an appreciable chance that someone like Danny exposed to that excessively neurovirulent vaccine would contract polio.

government's regulatory violations proximately caused Danny's injury." *United States v. St. Louis University,* 336 F.3d at 304.

By forcing that impossible proximate cause standard on plaintiff, the 2-1 Panel guaranteed that the Government regulator will always escape liability for violating its mandatory federal safety regulations which are enacted to protect the innocent children who are required to be immunized.

EXISTENCE OF JURISDICTION IN COURTS BELOW

This contribution action was commenced in the United States District Court for the District of Maryland. The District Court has jurisdiction over the matter pursuant to the FTCA, 28 U.S.C. § 1346.

The District Court granted partial summary judgment in favor of SLU on January 25, 2002. *St. Louis University v. United States*, 182 F. Supp.2d 494 (D. Md. 2002). The District Court certified the order as appropriate for immediate review, and the United States Court of Appeals for the Fourth Circuit granted the Government permission to bring interlocutory appeal under 28 U.S.C. § 1292(b). On July 16, 2003, the Fourth Circuit reversed the District Court's grant of partial summary judgment in favor of SLU, and directed entry of final judgment in favor of the Government. *United States v. St. Louis University,* 336 F.3d 294 (4th Cir. July 16, 2003).

ARGUMENT FOR ALLOWANCE OF THE WRIT

By rejecting the binding precedent of the Supreme Court in *Berkovitz* and the Fourth Circuit in *Sabin IV,* and thereby disregarding the fundamental doctrine of *stare decisis*, the Fourth Circuit panel below decision

radically departs from traditional federal practice. *See* Sup. Ct. R. 10(a) (review on certiorari warranted where decision "so far departed from the accepted and usual course of judicial proceedings . . . as to call for an exercise of this Court's supervisory power"). Moreover, by shielding the federal Government from FTCA liability for violating the mandatory federal vaccine regulations by releasing the noncompliant vaccine, the Fourth Circuit panel decision below conflicts with the precedent of the Third,[12] Sixth,[13] Eighth[14] and Ninth Circuits,[15] which all subjected the Government to FTCA liability for violating these mandatory federal regulations. *See* Sup. Ct. R. 10(a) (review on certiorari warranted where "a United States court of appeals has entered a decision in conflict with the decision of another United States court of appeals on the same important matter"). Indeed, this Court in *Berkovitz*, *supra*, granted certiorari because of the conflict among the then Third, Sixth, Eighth, and Ninth Circuits.

This Court should now grant certiorari to review and reverse the 2-1 Fourth Circuit Panel decision. By holding that the Government is liable for concededly violating mandatory federal vaccine safety regulations, which necessarily increased the risk of harm to those receiving the OPV vaccine, the Supreme Court would restore uniformity to the federal vaccine regulatory system and uphold public confidence in the regulatory process and the rule of law itself. The law ought not to shield the Government from liability by creating proxi-

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12 *Berkovitz by Berkovitz v. United States*, 858 F.2d 122 (3d Cir. 1988) (*on remand*); *Griffin v. United States*, 500 F.2d 1059 (3d Cir. 1974)

13 *Schindler v. United States*, 661 F.2d 552, 560 (8th Cir. 1981)

14 *Loge v. United States*, 662 F.2d 1268 (8th Cir. 1981)

15 *Baker v. United States*, 817 F.2d 560 (9th Cir. 1987)

mate cause standards that are practically and intellectually impossible to satisfy.

I. In A Radical Departure From Traditional Federal Practice That Warrants Correction By The Supreme Court, The Fourth Circuit Panel Disregarded The Binding United States Supreme Court Precedent Of *Berkovitz* That Subjected The Federal Government To Liability For Violating Mandatory Federal OPV Safety Regulations.

In *Berkovitz v. United States*, 486 U.S. 531 (1988), the Government was sued under the FTCA for releasing the excessively neurovirulent Orimune vaccine in violation of the federal OPV safety regulations. The Government sought to escape liability under the FTCA's discretionary function exception, which "marks the boundary between Congress' willingness to impose tort liability upon the United States and its desire to protect certain governmental activities from exposure to suit by private individuals." *Id.* at 536. Rejecting the application of the exception, the *Berkovitz* Court set forth a fundamental principle of the federal regulatory system: "The discretionary function exception will not apply when a federal statute, regulation, or policy specifically prescribes a course of action for an employee to follow. In this event, *the employee has no rightful option but to adhere to the direction.*" *Id.* at 536. (emphasis added). This Court found that even that Government conceded that federal officials would have violated mandatory federal regulations by releasing a noncompliant vaccine.[16] The *Berkovitz* Court subjected the Government to tort lia-

[16] As put by the Court, "[t]he Government's own argument [concedes] that if an employee knew that a lot did not comply with these standards, he would have no discretion to approve the release of the lot." *Berkovitz*, 486 U.S. at 547 n.13.

bility under the FTCA for releasing the oral polio vaccine in violation of its own regulations: "if the Bureau's policy did not allow the official who took the challenged action to release a noncomplying lot on the basis of policy considerations—the discretionary function exception does not bar the claim." *Id.* at 547.

In the present case, it is undisputed and undisputable that federal officials violated the mandatory federal OPV regulations by releasing the noncompliant vaccine that paralyzed Danny: "in taking the actions they did, they increased the risk that several more individuals would contract polio as a result of exposure to OPV than would have done if the OPV regulations had been strictly followed" *St. Louis University v. United States*, 182 F. Supp.2d at 503. *See also Sabin III*, 774 F. Supp. at 957:

> The fact remains that they approved vaccine exceeding the neurovirulence criteria which had been established in the regulations as a means for defining acceptable risk. They were fully aware that the vaccine did not pass the regulatory tests. . . . In short, DBS officials arrogated to themselves the power to define what constituted an acceptable risk, thereby undermining the rule of law and threatening long-term public confidence in the regulatory system itself.

Notwithstanding that flagrant disregard of mandatory federal OPV safety regulations, notwithstanding that "the Bureau's policy did not allow the official who took the challenged action to release a noncomplying lot on the basis of policy considerations," *Berkovitz*, 486 U.S. at 547, notwithstanding that three-month old Danny Callahan would not have been paralyzed if the Government had not released the Orimune vaccine in violation of its own mandatory OPV regulations, the 2-1 Panel

decision below enabled the Government to escape FTCA liability. *United States v. St. Louis University*, 336 F.3d at 303. As discussed above, the Fourth Circuit imposed an unprovable proximate cause standard, and then reversed and ordered final judgment in favor of the Government on the sole ground that plaintiff did not prove that unprovable proximate cause standard. *Id.*

By shielding the Government from FTCA liability, this Fourth Circuit decision rejects binding Supreme Court *Berkovitz* precedent that subjects the Government to FTCA liability for violating its own mandatory OPV safety regulations by releasing the excessively neurovirulent vaccine. Accordingly, this Court should now grant certiorari to correct the Fourth Circuit for "so far depart[ing] from the accepted and usual course of judicial proceedings" by rendering this decision in disregard of binding Supreme Court precedent, *stare decisis*, and the proper order of our federal judicial system. Sup. Ct. R. 10(a).

II. In A Radical Departure From Traditional Federal Practice That Warrants Correction By The Supreme Court, The Fourth Circuit Panel Disregarded The Binding Fourth Circuit Precedent Of *Sabin IV* That Subjected The Federal Government To Liability For Violating Mandatory Federal OPV Safety Regulations.

In addition to improperly rejecting the binding Supreme Court precedent of *Berkovitz*, the Fourth Circuit panel below flouts the fundamental doctrine of *stare decisis* by rejecting the binding Fourth Circuit precedent of *Sabin IV*. *See Sabin IV*, 984 F.2d at 128 (4th Cir. 1993) (holding government did proximately cause and was liable for plaintiffs' paralytic poliomyelitis by releasing Orimune in violation of mandatory federal

neurovirulence regulations);*United States v. St. Louis University*, 336 F.3d at 303-04 (4th Cir. 2003) (holding government did *not* proximately cause and not liable for plaintiff's paralytic poliomyelitis by releasing Orimune in violation of mandatory federal neurovirulence regulations).

The Fourth Circuit panel "has no basis on which to reach the conclusion it reaches other than it disagrees with the reasoning [of] *Sabin IV*." *United States v. St. Louis University*, 336 F.3d at 305 (Luttig, J., dissenting). The Fourth Circuit panel's rejection of the doctrine of *stare decisis*—"of fundamental importance to the rule of law"[17]—is inexplicable unless the panel simply did not like the *result* of holding the Government liable for violating the mandatory OPV regulations. But adherence to precedent promotes stability, predictability, and respect for judicial authority. *Hilton* at 202; *Vasquez v. Hillery*, 474, U.S. 254, 265-266 (1986). Ignoring that teaching, the 2-1 Panel decision below rendered a decision that rejected the binding precedent of *Sabin IV*. As put by Judge Luttig in his cogent dissent:

> *Sabin IV* binds us as a matter of federal law. . . . Under this binding precedent, we are required to conclude that the district court's identical reasoning here is likewise a proper proximate cause analysis. . . . *Sabin IV* decided the matter and so provides binding reasoning, which . . . would result in affirmance of the district court's judgment. Indeed, the rule we face not only binds us, but also every district court within our circuit and every future panel of our court.

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[17] *Hilton v. South Carolina Pub. Rys. Comm'n*, 502 U.S. 197, 202 (1991); *Welch v. Texas Dept. of Highways and Public Transp.*, 483 U.S. 468, 494 (1987).

United States v. St. Louis University, 336 F.3d at 305-07. (Luttig, J., dissenting).

By flouting the fundamental principle of *stare decisis* by rejecting the binding precedent of *Sabin IV*, the 2-1 Fourth Circuit panel "so far departed from the accepted and usual course of judicial proceedings" as to warrant review and reversal by the Supreme Court on certiorari. Sup. Ct. R. 10(a).

III. The Fourth Circuit's Decision Shielding The Government From Liability Conflicts With Third Circuit Precedent Subjecting the Government To Liability For Violating Mandatory Federal OPV Safety Regulations, And Thereby Undermines Uniform Application Of Federal OPV Regulations.

On remand, the Third Circuit in *Berkovitz by Berkovitz v. United States*, 858 F.2d 122 (3d Cir. 1988), refused to let the Government hide behind the FTCA discretionary function exception where "notwithstanding the Bureau's adoption of a policy of testing all vaccine lots to see if they comply with the safety standards and preventing the release of a non-complying lots, the Bureau's employees knowingly approved the release of a non-complying lot." *Id.* at 124. Applying the Supreme Court's instruction, the Third Circuit found that the Government's deliberate release of the excessively neurovirulent Orimune vaccine in violation of the mandatory federal neurovirulence regulations "involved no policy discretion" and was therefore not protected from suit. *Id.* Accordingly, the Third Circuit subjected the Government to FTCA liability for releasing the excessively neurovirulent Orimune vaccine that paralyzed plaintiff. *Id.*

Likewise, the Third Circuit in *Griffin v. United States*, 500 F.2d 1059 (3d Cir 1974), held the FTCA discre-

tionary function exception did not shield the Government from liability for violating the mandatory federal neurovirulence regulations by releasing the excessively neurovirulent vaccine *Id.* at 1069. The Third Circuit found that the Government had "acted outside the scope of the authority conferred by the regulation" by releasing the excessively neurovirulent vaccine in "disregard [of] the mandatory federal regulation." *Id.* at 1069. Accordingly, because "no discretion was conferred to disregard the mandatory regulatory command," the Third Circuit held "that the Government may be liable where its employees . . . fail to conform to pre-existing statutory and regulatory requirements" by releasing the excessively neurovirulent vaccine. *Id.*

In contrast, the 2-1 Fourth Circuit panel below enabled the Government to escape FTCA liability, *see United States v. St. Louis University,* 336 F.3d at 303 (imposing unprovable proximate cause standard), even though Government officials "failed to conform to . . . the mandatory regulatory command" of the OPV neurovirulence regulations when they "knowingly approved the release of a non-complying lot." *Griffin*, 500 F.2d at 1069 (3d Cir 1974); *Berkovitz by Berkovitz v. United States*, 858 F.2d at 124 (3d Cir. 1988) (subjecting Government to FTCA liability). This Fourth Circuit precedent shielding the Government from FTCA liability thus conflicts with the Third Circuit *Berkovitz* and *Griffin* precedent subjecting the Government to FTCA liability for violating its own mandatory regulations by releasing the excessively neurovirulent vaccine. Accordingly, this Court should now grant certiorari to resolve this conflict. *See* Sup. Ct. R. 10(a) (review on certiorari appropriate where "a United States court of appeals has entered a decision in conflict with the decision of another United States court of appeals on the same important matter").

IV. The Fourth Circuit's Decision Shielding The Government From Liability Conflicts With Sixth Circuit Precedent Refusing To Shield The Government From Liability For Violating Mandatory Federal OPV Safety Regulations, And Thereby Undermines Uniform Application Of Federal OPV Regulations.

In *Schindler v. United States*, 661 F.2d 552 (6th Cir. 1981), a polio victim asserted that federal government officials wrongfully approved the licensing, manufacture and distribution of Orimune polio vaccine that caused plaintiff to contract paralytic poliomyelitis, without requiring the private manufacturer to comply with federal OPV safety regulations. *Id.* at 554. The district court dismissed the complaint on the ground that the Government was immune from FTCA liability under restrictive State rules of government immunity for municipal corporations. *Id.* at 557. Reversing, the Sixth Circuit refused to limit the Government's FTCA liability because of restrictive State rules of immunity:

> It is, therefore, self-defeating and illogical to hold that the United States may have waived its immunity with regard to a particular act because it is not a discretionary function, and then to turn to the law of the state and incorporate the means by which it has chosen to solve this same problem of preserving this necessary "vestige of government immunity. As the [Supreme] Court held in *United States v. Muniz*, it is "improper to limit suits (under the FTCA) because of restrictive state rules of immunity." 374 U.S. 150, 164 (1963).

Schindler, 661 F.2d at 560.

In contrast, 2-1 Fourth Circuit panel below allowed the Government to escape FTCA liability for violating the federal OPV safety regulations by wrongfully

approving the manufacture and distribution of Orimune vaccine that caused plaintiff to contract paralytic poliomyelitis. *See United States v. St. Louis University,* 336 F.3d at 303 (imposing unprovable proximate cause standard). This Fourth Circuit precedent that shields the Government from FTCA liability thus conflicts with the Sixth Circuit *Schindler* precedent that refused to shield the Government from FTCA liability for violating its own regulations by approving the manufacture and release of the Orimune vaccine. Accordingly, this Court should now grant certiorari to resolve this conflict. *See* Sup. Ct. R. 10(a), *supra.*

V. The Fourth Circuit's Decision Shielding The Government From Liability Conflicts With Eighth Circuit Precedent Subjecting the Government To Liability For Violating Mandatory Federal OPV Safety Regulations, And Thereby Undermines Uniform Application Of Federal OPV Regulations.

The Eighth Circuit in *Loge v. United* States, 662 F.2d 1268 (8th Cir. 1981), held the FTCA discretionary function exception did not shield the Government for violating the mandatory federal OPV regulations. *Id.* at 1272-73. The *Loge* Court found that the Government "has no discretion to disregard the mandatory regulatory commands pertaining to criteria a vaccine must meet before . . . releasing a particular lot of vaccine for distribution to the public." *Id.* at 1273. Moreover, the *Loge* Court found that the Government breached its duty to plaintiff under the Good Samaritan doctrine of Section 324A of the Restatement (Second) of Torts by violating its own mandatory safety regulations by releasing the excessively neurovirulent Orimune vaccine:

> [T]he Government increased the risk of harm to the Loges by licensing an allegedly untested product,

> Orimune, and by releasing to the public an allegedly untested or negligently tested lot of that vaccine: if either the product itself or a particular lot of that product failed to conform to the standards established by the regulations, then proper testing or proof of testing would have revealed the nonconformity and the vaccine would never have been disseminated to Todd Loge. Likewise, it can be said that the Government undertook a duty owed by the drug manufacturer to the Loges when it required that proof of the drug's safety be demonstrated to the Government before releasing it to the public.

Loge, 662 F.2d at 1274.[18]

Accordingly, the Eighth Circuit subjected the Government to liability "under the FTCA" for releasing the excessively neurovirulent Orimune vaccine in "violation of its own regulations." *Id.* at 1275.

In contrast, 2-1 Fourth Circuit panel below allowed the Government to escape FTCA liability, *see United States v. St. Louis University*, 336 F.3d at 303 (imposing unprovable proximate cause standard), even though Government officials "failed to conform to the standards established by the regulations" when they "approv[ed] for release the particular vaccine that was eventually administered" to Danny Callahan. *See Loge*, 662 F.2d at 1274. This Fourth Circuit precedent that shields the Government from FTCA liability thus conflicts with the Eighth Circuit *Loge* precedent that subjects the Gov-

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[18] *See also, St. Louis University v. United States*, 182 F. Supp.2d at 502 (by approving excessively neurovirulent Orimune vaccine in violation of "the OPV regulations, the United States had breached its duty to the members of the public, which it had assumed by virtue of its undertaking to regulate a potentially hazardous condition for the benefit of others" under the Good Samaritan doctrine of § 324A of the Restatement (Second) of Torts).

ernment to FTCA liability for violating its own regulations by releasing the excessively neurovirulent vaccine. Accordingly, this Court should now grant certiorari to resolve this conflict. *See* Sup. Ct. R. 10(a), *supra.*

VI. The Fourth Circuit's Decision Shielding The Government From Liability Conflicts With Ninth Circuit Precedent Subjecting the Government To Liability For Violating Mandatory Federal OPV Safety Regulations, And Thereby Undermines Uniform Application Of Federal OPV Regulations.

The Ninth Circuit in *Baker v. United* States, 817 F. 2d 560 (9th Cir. 1987), held the FTCA discretionary function exception did not "insulate the Government from liability" for its "negligent failure to obey a mandatory regulatory command" by licensing and releasing the non-compliant vaccine. *Id.* at 566. The *Baker* Court found that Government officials had no discretion to violate mandatory OPV safety regulations "that serve to protect susceptible persons from contracting the [polio] disease." *Id.* at 561. Accordingly, *Baker* concluded that the Government "may be subjected to tort liability for the alleged negligence of an agency employee in failing to follow a specific mandatory [OPV] regulation," because the Government's "failure to follow its own [OPV] regulatory commands" is ***not*** "the type of decision that Congress intended to shield from tort liability." *Id.* at 563-64.

Yet "shield from tort liability"[19] the Government for violating its own OPV regulations by for releasing the Orimune vaccine is exactly what the Fourth Circuit below did when it imposed an unprovable proximate cause standard on plaintiff. *United States v. St. Louis*

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[19] *Baker*, 817 F. 2d at 563.

University, 336 F.3d at 303. This Fourth Circuit precedent that shields the Government from FTCA liability thus conflicts with the Ninth Circuit *Baker* precedent that subjects the Government to FTCA liability for violating its own mandatory federal OPV safety regulations by releasing the excessively neurovirulent vaccine. Accordingly, this Court should now grant certiorari to resolve this conflict. *See* Sup. Ct. R. 10(a), *supra*.

CONCLUSION

For the reasons set forth above, this petition for certiorari should be granted.

Respectfully submitted,

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